United States District Court
Northern District of California

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

EDWIN STREED, et al., Plaintiffs, v. EON LABS, INC.., et al., Defendants.	Case No. 17-cv-02609-MMC **ORDER GRANTING PLAINTIFFS' MOTION TO REMAND; DENYING PLAINTIFFS' REQUEST FOR ATTORNEYS' FEES AND COSTS** Re: Dkt. No. 60
JOHN W. BLACKFORD, et al., Plaintiffs, v. WYETH PHARMACEUTICAL, INC., et. al., Defendants.	Case No. 17-cv-03825-MMC **ORDER GRANTING PLAINTIFFS' MOTION TO REMAND; DENYING PLAINTIFFS' REQUEST FOR ATTORNEYS' FEES AND COSTS** Re: Dkt. No. 20

Before the Court are two motions to remand: (1) plaintiffs' Motion to Remand Action to Alameda County Superior Court, filed May 31, 2017, in Case No. 17-2609; and (2) plaintiffs' Motion to Remand Action to Sonoma County Superior Court, filed July 7, 2017, in Case No. 17-3285. Both motions have been fully briefed. Having considered the parties' written submissions, the Court rules as follows.[1]

BACKGROUND

Plaintiffs are 113 individuals who allege they have been injured by their, or their spouses or decedents', use of products "manufactured, promoted, supplied and/or distributed by" defendants. (See First Amended Compl., Case No. 17-2609 (hereinafter "Streed FAC") ¶¶ 1-39; Compl., Case No. 17-3825 (hereinafter "Blackford Compl.") ¶¶ 1-

[1] By order filed August 14, 2017, the Court took the matter under submission.

36). In particular, plaintiffs allege they were "diagnosed as suffering from atrial fibrillation" and were prescribed and thereafter "purchased and ingested" amiodarone hydrochloride, a "drug commonly referred to as [a]miodarone," and, "as a proximate cause thereof," developed various "life-threatening and debilitating" conditions, including, but not limited to, pulmonary fibrosis, lung disease, and vision loss. (See Streed FAC ¶¶ 1-39; Blackford Compl. ¶¶ 1-36.).[2]

Defendant Wyeth Pharmaceuticals, Inc. ("Wyeth") is named as the initial manufacturer of amiodarone in the United States; defendant McKesson Corporation ("McKesson") is named as the primary distributor of amiodarone; and the remaining defendants (collectively, "Generic Defendants") are named as manufacturers of generic formulations of amiodarone. (See Streed FAC ¶ 50, 66, 70; Blackford Compl. ¶ 47, 63, 67.)

In 1985, the Food and Drug Administration ("FDA") approved Wyeth's application to "market and sell" the brand name version of amiodarone. (See Streed FAC ¶ 66; Blackford Compl. ¶ 63.) Plaintiffs allege amiodarone "was approved by the FDA only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia," but that Wyeth "instituted and maintained an aggressive marketing plan positioning [a]miodarone as a 'first-line'" treatment "for atrial fibrillation, . . . and failed to warn prescribing physicians of the potential dangers associated with [a]miodarone toxicity and danger to atrial fibrillation patients." (See Streed FAC ¶¶ 67-68; Blackford Compl. ¶¶ 64-65.) Plaintiffs further allege Generic Defendants "took advantage of Wyeth's aggressive marketing plan" and "actively promoted their generic [a]miodarone in the stream of commerce for the 'off-label' uses openly promoted by Wyeth." (See Streed FAC ¶¶ 71, 118; Blackford Compl. ¶¶ 68,

[2] The operative complaints refer to all named plaintiffs, whether a patient, spouse, or estate, collectively as "plaintiffs." (See, e.g., Streed FAC ¶ 73 (alleging "[p]rior to being prescribed [a]miodorane, [p]laintiffs were diagnosed with atrial fibrillation"); Blackford Compl. 73 (same).) For ease of reference, the Court does so as well herein.

115.)[3]

Additionally, plaintiffs allege, the FDA required that "any person who was prescribed [amiodarone] was to first receive a 'Medication Guide,'" the distribution of which "was the responsibility of all [d]efendants," and that defendants failed "to provide the Medication Guide," or, "in the case of McKesson, to distribute it and ensure its distribution." (See Streed FAC ¶¶ 67, 74; Blackford Compl. ¶¶ 64, 71.)

According to plaintiffs, each of the defendants "continued to actively conceal and understate the drug's nature and adverse risks . . . , despite [its] duty to disclose such information and the need to distribute and ensure distribution of the Medication Guides," failed to disclose "specific material adverse information" to "the FDA, healthcare professionals, consumers, and [p]laintiffs," and "continued [its] fraudulent marketing, promotional, and sales practices," in spite of "FDA warnings and thousands of adverse patient experiences." (See Streed FAC ¶¶ 108, 116, 120; Blackford Compl. ¶ 105, 113, 117.)

Based on the above allegations, plaintiffs assert eight Causes of Action, titled, respectively: "Strict Product Liability – Failure to Warn," "Negligence – Failure to Warn," "Negligence –Marketing and Sale," "Negligence Per Se," "Fraud and Deceit," "Violation of Cal. Bus. & Prof. Code §§ 17200," "Violation of Cal. Civil Code §§ 1750, et seq.," and "Wrongful Death."

On May 5, 2017 and July 5, 2017, respectively, Case No. 17-2609 and Case No. 17-3825 were removed from state court on the asserted basis of federal question jurisdiction, namely, that plaintiffs' claims are either "inherently federal in nature," or "raise questions that are, in and of themselves, both substantial and disputed questions of federal law". (See Not. Removal, Case No. 17-2609 (hereinafter "Streed Not. Removal"),

[3] As alleged by plaintiffs, "off-label" use is "[a]ny specifically prescribed use beyond those approved by the FDA" and promotion of a drug for off-label use is subject to "strict requirements" that Wyeth and the Generic Defendants did not follow. (See Streed Compl. ¶ 69; Blackford Compl. ¶ 66.)

¶ 18); Not. Removal (hereinafter "Blackford Not. Removal"), ¶ 18.)

By the instant motions, plaintiffs seek remand on the ground that they have alleged no federal claims and that their state law claims do not raise federal issues sufficiently significant to confer federal question jurisdiction.

LEGAL STANDARD

Where a case has been removed from state court and "at any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case shall be remanded." See 28 U.S.C. § 1447(c). The Court is required to "strictly construe the removal statute against removal jurisdiction," and "[f]ederal jurisdiction must be rejected if there is any doubt as to the right of removal in the first instance." See Gaus v. Miles, Inc., 980 F.2d 564, 566 (9th Cir. 1992). The removing defendant "always has the burden of establishing that removal is proper." See id.

DISCUSSION

District courts have federal question jurisdiction over "all civil actions arising under the Constitution, laws or treaties of the United States." See 28 U.S.C. § 1331. There are "two ways" in which a case can "'arise under' federal law" and thus be subject to federal question jurisdiction. See Gunn v. Minton, 568 U.S. 251, 257 (2013) (alteration omitted). First, and "[m]ost directly, a case arises under federal law when federal law creates the cause of action asserted." See id. Second, "even where a claim finds its origins in state rather than federal law," federal question jurisdiction will still lie where "a state law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." See id. (quoting Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg., 545 U.S. 308, 314 (2005)).

Here, the parties dispute whether the instant cases "arise under" federal law in either of the above-discussed ways.

A. Federal Cause of Action as Basis for Jurisdiction

As noted, the first way in which a case may "arise under" federal law is where

"federal law creates the cause of action asserted." See Gunn, 568 U.S. at 275. Here, defendants point out, each complaint "on its face expressly and repeatedly references and incorporates federal law" (see Opp., Case No. 17-2609 (hereinafter "Streed Opp."), at 5:19-20; Opp., Case No. 17-3825 hereinafter "Blackford Opp."), at 5:19-20), in particular, the federal Food Drug and Cosmetic Act ("FDCA") and its implementing regulations. Where, as here, however, a plaintiff has "chosen to seek relief" solely under state statutory and common law, the fact that the complaint makes "repeated references to" a federal statute "does not mean [such statute] creates the cause of action under which [he/she] sues." See ARCO Envtl. Remediation, L.L.C. v. Dep't Health & Envtl. Quality Mont., 213 F.3d 1108, 1133 (9th Cir. 2000).

Nevertheless, as defendants also point out, a plaintiff "cannot compel a remand simply because they disclaim having specifically pled a federal cause of action" (see Streed Opp. at 6:3-4; Blackford Opp. at 6:6-8), i.e., where they engage in "artful pleading," see ARCO, 213 F.3d at 1114.

Accordingly, the Court next turns to defendants' second argument in support of removal.

B. Federal Issues within State Law Claims as Basis for Jurisdiction

As set forth by the Supreme Court in Gunn, federal jurisdiction "will lie" where a state law claim raises a federal issue that is "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." See Gunn, 568 U.S. at 258. "Where all four of these requirements are met, . . . jurisdiction is proper." See id.

Here, defendants contend plaintiffs' state law claims raise two federal issues that meet the above four requirements: (1) violation of the FDCA and its implementing regulations governing Medication Guides; and (2) violation of the FDCA by promotion of off-label use.

The Court next addresses whether either issue meets the four requirements.

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1. Necessarily Raised

As the Supreme Court observed in Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804 (1986), "the mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction." See id. at 813. "[F]ederal law is not a necessary element" of a state law claim where the claim "can be supported by alternative and independent theories—one of which is a state law theory and one of which is a federal law theory." See Rains v. Criterion Sys., Inc., 80 F.3d 339, 346 (9th Cir. 1996).

Here, plaintiffs allege claims for strict products liability, negligence, fraud, and wrongful death, as well as claims under California's Unfair Competition Law ("UCL") and Consumer Legal Remedies Act ("CLRA"), each of which can be supported by a theory independent of any violation of federal law or regulation.

In particular, one independent theory on which plaintiffs' fraud, UCL, and CLRA claims are predicated is common law fraud, namely, defendants' affirmative misrepresentations as to the nature and intended use of amiodarone and failure to disclose material facts about its side effects. (See, e.g., Streed FAC ¶¶ 116, 132, 135, 178-185, 193-95, 202-203; Blackford Compl. ¶¶ 113, 129, 132, 175-182, 190-92, 199-200.) Similarly, an independent theory on which plaintiffs' strict products liability, negligence, and wrongful death claims are predicated arises under the common law, namely, defendants' breach of their duty to adequately warn of known risks and to market and sell a safe product. (See Streed FAC ¶¶ 108, 149-52, 157-59, 165, 207; Blackford Compl. ¶¶ 105, 146-49, 154-56, 162, 204.) [4]

[4] Although plaintiffs' Fourth Cause of Action, titled "Negligence Per Se," is based on an alleged violation of a federal regulation governing distribution of Medication Guides, negligence per se "is not a separate cause of action," see Millard v. Biosources, Inc., 156 Cal. App. 4th 1338, 1353 n.2 (2007), but, rather, a legal concept that "raises a [rebuttable evidentiary] presumption that the violator was negligent," see Jacobs Farm/Del Cabo, Inc. v. Western Farm Serv., Inc., 190 Cal. App. 4th 1502, 1526 (2010) (citing Quiroz v. Seventh Ave. Center, 140 Cal. App. 4th 1256, 1285-86 (2006) (explaining negligence per se is an "evidentiary presumption" that "may be rebutted")); see also Johnson v. Honeywell Int'l, Inc., 179 Cal. App. 4th 549, 558 (2009) ("Under the doctrine of negligence per se, the plaintiff 'borrows' statutes to prove duty of care and

Consequently, the Court finds the first requirement has not been met.

2. Actually Disputed

The parties disagree as to the interpretation of 21 C.F.R. § 208.24, the regulation governing distribution of the Medication Guides. Neither party has clarified whether there is any dispute as to defendants' alleged promotion of off-label uses.

Consequently, the Court finds the second requirement has been met as to at least one federal issue.

3. Substantial

For a federal issue to be substantial, "it is not enough that [it] be significant to the particular parties in the immediate suit"; rather, the issue must be important "to the federal system as a whole." See Gunn, 568 U.S. at 260.

In that regard, the Court notes that the two cases cited in Gunn as providing examples of a substantial federal issue involved, respectively, a challenge to the actions of a federal agency and the validity of a federal law. See Grable, 545 U.S. at 314-15 (finding, where case turned on whether Internal Revenue Service had provided plaintiff with "adequate notice, as defined by federal law," federal government had "a direct interest in the availability of a federal forum to vindicate its own administrative action"); Smith v. Kansas City Title & Trust Co., 255 U.S. 180, 201 (1921) (finding, where shareholder challenged "validity" of securities issued by federal government, "constitutional validity of an act of Congress" was "directly drawn into question"). Here, plaintiffs challenge only the behavior of private parties, not the actions of the FDA or the validity of the FDCA and/or its implementing regulations, and, consequently, have not raised an issue of "importance . . . to the federal system as a whole." See Gunn, 568 U.S. at 260; see also Carmine v. Poffanbarger, 154 F. Supp. 3d 309, 318 (E.D. Va. 2015) (holding dispute as to "whether medical manufacturers designed, manufactured, and

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standard of care.") (internal citation omitted). As such, it assists a plaintiff in proving a negligence claim, but is not a required element thereof.

promoted an unreasonably dangerous product" does "not affect the operation of the federal system in the way that was evident in Smith or in Grable").

Additionally, as plaintiffs point out, the plaintiffs in Merrell Dow based their negligence claim on an alleged violation of the FDCA, and the Supreme Court, noting "there is no federal cause of action for FDCA violations," see Merrell Dow, 478 U.S. at 810, held the absence of a "federal remedy for the violation of this federal statute is tantamount to a congressional conclusion that the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently 'substantial' to confer federal-question jurisdiction," see id. at 814. Although, in Grable, the Supreme Court later clarified that Merrell Dow should not be read as holding the absence of a federal private right of action is dispositive, the Grable Court also acknowledged the potential significance of such absence on the "assessment of substantiality." See Grable, 545 U.S. at 318. As Merrell Dow has made that assessment with respect to state law claims alleging violations of the FDCA, the Court finds Merrell Dow "governs the present question" as to the substantiality of the federal issues presented here.[5] See In re. Avandia Marketing, Sales Practices & Prods. Liab. Litig., 624 F. Supp. 2d 396, 415-16 (E.D. Pa. 2009) (citing Merrell Dow as controlling; finding, where plaintiffs alleged "Negligence – Failure to Warn" claim that "explicitly refer[red] to the FDCA as well as certain implementing administrative regulations," federal issue was "not . . . sufficiently substantial" to confer federal question jurisdiction).

Consequently, the Court finds the third requirement has not been met.

4. Capable of Resolution Without Disrupting Federal-State Balance

Lastly, even if all of the above three requirements had been met, defendants must show the federal issues presented here are "capable of resolution in federal court without

[5] To the extent plaintiffs here allege noncompliance with regulations promulgated under the FDCA, such allegations necessarily allege a violation of the FDCA itself, namely, that such noncompliance constitutes "distribution of a mislabeled and illegal drug." (See Streed FAC ¶ 74; Blackford Compl. ¶ 71); see also 21 U.S.C. § 352(a)(1).

disrupting the federal-state balance approved by Congress." See Gunn, 568 U.S. at 258.

In Merrell Dow, the Supreme Court addressed this requirement as well, "empasiz[ing] . . . it would flout congressional intent to provide a private federal remedy for the violation of the [FDCA]," and holding "it would similarly flout, or at least undermine, congressional intent to conclude that the federal courts might nevertheless exercise federal-question jurisdiction and provide remedies for violations of that federal statute solely because the violation of the federal statute is said to be a 'rebuttable presumption' [of negligence] . . . under state law." See Merrell Dow, 478 U.S. at 812; see also Grable, 545 U.S. at 318 (acknowledging "the combination of no federal cause of action and no preemption of state remedies for misbranding as an important clue to Congress's conception of the scope of the jurisdiction to be exercised under § 1331"; noting, "exercising federal jurisdiction over a state misbranding action would have attracted a horde or original filings and removal cases raising other state claims with embedded federal issues").

The Supreme Court's reasoning in Merrell Dow and Grable applies equally to the issues presented here. The Court finds unpersuasive defendants' argument that, to the extent plaintiffs' claims allege a failure to supply an accompanying Medication Guide, there is little risk of disrupting the federal-state balance because such claims are rare. Were the Court to find federal jurisdiction appropriate in this instance, such ruling "arguably would apply further," see Carmine, 154 F. Supp. at 319, and essentially would "invite all similar claims involving FDA-approved drugs into federal courts across the country," see Arnold v. Baxter Healthcare Corp., 609 F. Supp. 2d 712, 718 (N.D. Ohio 2009) (noting "any products liability case involving FDA-approved drugs will likely involve the FDCA").

Consequently, the Court finds the fourth requirement, as with the first and third, has not been met.

In sum, the Court lacks federal question jurisdiction over the above-titled cases and, accordingly, remand is appropriate.

C. Attorneys' Fees and Costs

Plaintiffs ask the Court for an award of the attorneys' fees and costs they incurred in seeking remand. An "order remanding the case may require payment of just costs and any actual expenses, including attorney fees, incurred as a result of the removal." See 28 U.S.C. § 1447(c). "[A]bsent unusual circumstances," however, "attorney's fees should not be awarded when the removing party has an objectively reasonable basis for removal." See Martin v. Franklin Capital Corp., 546 U.S. 132, 141 (2005). Here, the Court finds an award of fees is not warranted. Although, as discussed above, the Court was not persuaded by defendants' arguments, the Court does not find those arguments were objectively unreasonable, and plaintiffs have not shown defendants sought removal "for the purpose of prolonging litigation." See id. at 140.

CONCLUSION

For the reasons set forth above, plaintiffs' motions to remand are hereby GRANTED, and plaintiffs' requests for fees and costs are hereby DENIED. In light thereof, Case No. 17-2609 is hereby REMANDED to the California Superior Court for the County of Alameda, and Case No. 17-3825 is hereby REMANDED to the California Superior Court for the County of Sonoma.

The Clerk shall close the files.

IT IS SO ORDERED.

Dated: August 23, 2017

MAXINE M. CHESNEY
United States District Judge

United States District Court
Northern District of California